REMARKS

Reconsideration of the subject application is respectfully requested.

Pursuant to the Examiner's request, Applicants include with this Reply copies of pages 6 and 16 of the specification as filed. Applicants' representatives note that when Applicants' previous representatives provided Applicants' current representatives with a copy of the file history for the above-referenced application, pages 6 and 16 of the specification were missing from the file. However, the stamped postcard included with the Application papers provided by previous counsel indicates that the specification as filed was 81 pages, and as such would have included pages 6 and 16. A copy of the stamped postcard is provided.

Double Patenting Rejections

Upon indication of allowable subject matter, Applicants will file terminal disclaimers in response to each of the double patenting rejections.

Rejection of Claims 17-54 Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 17-54 stand rejected under 35 U.S.C. § 112, first paragraph, for purportedly not being enabled by the specification as filed for the use of DNA constructs comprising any seed specific promoter. Applicants respectfully disagree. Initially, Applicants would like to thank the Examiner for his indication that the specification does enable claims directed to the use of seed-specific promoters from Brassica, including napin, acyl, carrier proteins, and EA9 promoters. Moreover, "it is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art." *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991); *Application of Angstadt*, 537 F.2d 498, 503 (CCPA 1976). This is emphasized in *In re Hogan*, 559 F.2d 595 (CCPA 1977). In *Hogan*, the court found that the phrase "a solid polymer" in the claims included a crystalline form (specifically disclosed in the specification) and an amorphous form (which did not exist until almost nine years after filing of the first filed

application). The court stated "[t]o restrict appellants to the crystalline form disclosed, under such circumstances, would be a poor way to stimulate invention, and particularly to encourage its early disclosure. To demand such restrictions is merely to state a policy against broad protection for pioneer inventions..." *Id.* at 606.

The Federal Circuit expanded on *Hogan* in *Plant Genetic Systems, N.V. v. Dekalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003), when it stated "[w]e do not read *Hogan* as allowing an inventor to claim what was specifically desired but difficult to obtain at the time the application was filed, *unless the patent discloses how to make and use it*." *Id.* at 1340 (emphasis added). In the present application, Applicants do disclose how to isolate promoters from genes preferentially expressed in seed tissue, and how to use these seed-specific promoters in the constructs of the invention. See, for example, page 15, lines 25-33 (wherein transcription initiation regions for various genes preferentially expressed in seed tissue are disclosed); and page 62, line 27, to page 63, line 14 (wherein the identification of promoter regions from genes preferentially expressed in seed tissue is disclosed), of the specification as filed. Even though all possible seed-specific promoters that could be used in the present invention were not known at the time the specification was filed, the technology for identifying such promoters was available and disclosed.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 17-54 Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 17-54 have also been rejected under 35 U.S.C. § 112, first paragraph, for purportedly containing subject matter not described in the specification as filed in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention at the time the application was filed. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

The Examiner cites *University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997) as requiring a precise definition of the claimed subject matter, in this case a precise definition of the promoter sequence. Applicants note that more recent Federal Circuit decisions have distinguished *Lilly*. See, for example, *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002), where the court found that one should determine what one of skill in the art would glean from the written description. See also *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003), where the court cited *Enzo Biochem* as clarifying that:

> *Eli Lilly* did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.

Id. at 1332.

In the present application, Applicants do disclose how to isolate promoters from genes preferentially expressed in seed tissue, and how to use these seed-specific promoters in the constructs of the invention. See, for example, page 15, lines 25-33 (wherein transcription initiation regions for various genes preferentially expressed in seed tissue are disclosed); and page 62, line 27, to page 63, line 14 (wherein the identification of promoter regions from genes preferentially expressed in seed tissue is disclosed), of the specification as filed. The technologies used by the Applicants to identify regulatory regions and isolate promoters from genes preferentially expressed in seed tissue were disclosed in the application as filed.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 Under 35 U.S.C. § 103(a)

Claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Zambryski *et al.* (*EMBO J. 2*:2143-2150 (1983)) taken with Sengupta-Gopalan *et al.* (*Proc. Natl. Acad. Sci. USA 82*:3320-3324 (1985)). For at least all of the reasons set forth below, Applicants request withdrawal of this rejection.

Initially, Applicants have overcome the Enablement rejection (see above), and thus the claimed subject matter should be awarded the priority date of the parent application, which pre-dates the Sengupta-Gopalan *et al.* reference. Therefore, Sengupta-Gopalan *et al.* is not prior art to the present application.

Notwithstanding this, Zambryski *et al.* discloses a construct comprising promoter sequences from the Ti plasmid-specific nopaline synthase gene and coding sequences from nopaline synthase and a foreign gene contained in a pBR-like plasmid (see the paragraph bridging pages 2143 and 2144) and the transformation of tobacco, potato, carrot and petunia with such a construct. Zambryski *et al.*, in the paragraph bridging pages 2148 and 2149, discusses third-party references which purportedly disclose a vector comprising the nopaline synthase promoter and foreign coding sequences. However, Zambryski *et al.* does not disclose or even suggest a construct in which the promoter is from a gene preferentially expressed in seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, nor does it suggest methods of obtaining a plant using such a construct.

Even if taken in combination with Zambryski *et al.*, Sengupta-Gopalan *et al.* does not provide the motivation to make the constructs used in the methods of the claimed invention. Sengupta-Gopalan *et al.* discusses a construct comprising the phaseolin promoter and the phaseolin gene (or alternatively, the octopine synthase promoter and the phaseolin gene) (see page 3320, column 1, first paragraph). In addition, there would have been no expectation that the construct used in the methods of the claimed invention would be successful, as prior to the parent application being filed one of skill in the art would not have gleaned from these references that a seed specific promoter could be used to express genes heterologous to that promoter. In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

Rejection of Claims 20, 33, 38 and 41 Under 35 U.S.C. § 103(a)

Claims 20, 33, 38 and 41 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Zambryski *et al.* taken with Sengupta-Gopalan *et al.* and further in view of Pedersen *et al.* (*Plant Cell Reports 2(4)*:201-204 (1983)). For at least each of the reasons set forth below, withdrawal of this rejection is believed to be in order.

As discussed in more detail above, the teachings of Zambryski *et al.* in combination with the teachings of Sengupta-Gopalan *et al.* do not provide or motivate one of skill in the art to make the constructs used in the methods of claims 17, 18, 28, 34 and 39 (from which claims 20, 33, 38 and 41 depend). Claims 20, 33, 38 and 41 add the term that the plant is selected from the group consisting of soybean, rapeseed and tomato. The Examiner cites Pedersen *et al.* because it purportedly discloses the *Agrobacterium* mediated transformation of soybean plants. However, whatever else Pedersen *et al.* might disclose, it does not disclose or even suggest a construct in which the promoter is from a gene preferentially expressed in seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, nor does it disclose methods of using such constructs. Therefore, Pedersen *et al.* does not solve the deficiencies of Zambryski *et al.* and Sengupta-Gopalan *et al.* because even if the teachings of Pedersen *et al.* were combined with the teachings of both Zambryski *et al.* and Sengupta-Gopalan *et al.*, there would be no motivation to produce, or expectation of success of producing, a construct used in the methods of the claimed invention, in which the promoter is from a gene preferentially expressed in seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter. Therefore, Zambryski *et al.* in combination with Sengupta-Gopalan *et al.* and Pedersen *et al.* do not render obvious the claimed methods.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

Rejection of Claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 Under 35 U.S.C. § 103(a)

Claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Hall *et al.* (USP 5,504,200) taken with Sengupta-Gopalan *et al.* Applicants respectfully disagree.

Hall *et al.* discusses a construct for seed-specific expression comprising the phaseolin gene and promoter. As previously acknowledged by the Examiner, Hall *et al.* does not teach a construct comprising the phaseolin promoter (or other seed specific promoter) and a heterologous gene. Therefore, Hall *et al.* does not disclose or suggest a construct comprising, as operably linked components in the direction of transcription, a promoter region obtainable from a gene preferentially regulated in seed tissue; and a DNA sequence of interest, other than the native coding sequence of said gene.

Sengupta-Gopalan *et al.*, even if taken in combination with Hall *et al.*, would not motivate one of the art to produce or lead one of the art to expect success in producing the constructs used in the methods of the claimed invention. As noted above, Sengupta-Gopalan *et al.* discusses a construct comprising the phaseolin promoter and the phaseolin gene (or alternatively, the octopine synthase promoter and the phaseolin gene) (see page 3320, column 1, first paragraph). Sengupta-Gopalan *et al.* does not disclose or suggest a construct comprising, as operably linked components in the direction of transcription, a promoter region obtainable from a gene preferentially regulated in seed tissue; a DNA sequence of interest, other than the native coding sequence of said gene; and a transcription termination region. There was no expectation that the construct used in the methods of the claimed invention would be successful, as prior to the parent application being filed one of skill in the art would not have gleaned from these references that any promoter could be used to express genes heterologous to that promoter. In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

Rejection of Claims 20, 33, 38 and 41 Under 35 U.S.C. § 103(a)

Claims 20, 33, 38 and 41 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Hall *et al.*, taken with Sengupta-Gopalan *et al.* and further in view of Zambryski *et al.* taken with Pedersen *et al.* For at least each of the reasons set forth below, withdrawal of this rejection is believed to be in order.

As discussed in more detail above, Hall *et al.*, Zambryski *et al.* and Sengupta-Gopalan *et al.* do not disclose or even suggest the methods of claims 17, 18, 28, 34 and 39 (from which claims 20, 33, 38 and 41 depend). Specifically, even if the teachings of these references were taken together, there would be no motivation to produce a construct in which the promoter is from a gene preferentially expressed in seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, and therefore do not disclose or suggest methods of using such promoters. Claims 20, 33, 38 and 41 add the term that the plant is selected from the group consisting of soybean, rapeseed and tomato.

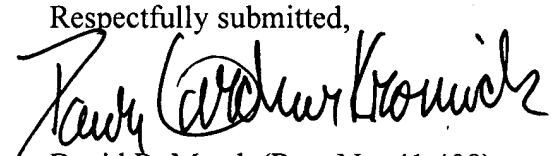
The Examiner cites Pedersen *et al.* because it purportedly discloses the *Agrobacterium* mediated transformation of soybean plants. However, whatever else Pedersen *et al.* might disclose, it does not disclose or even suggest a construct in which the promoter is from a gene preferentially expressed in seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, nor does it disclose methods of using such constructs. Therefore, as discussed, Pedersen *et al.* does not solve the deficiencies of Hall *et al.*, Zambryski *et al.* and Sengupta-Gopalan *et al.* because none of these references, even if taken together, would motivate one of skill in the art to produce or lead one of skill in the art to expect success in producing a construct in which the promoter is from a gene preferentially expressed in seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, nor do they disclose methods of using such constructs. Therefore, Hall *et al.* in combination with Sengupta-Gopalan *et al.*, Zambryski *et al.*, and Pedersen *et al.* do not render unpatentable the claimed methods.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

CONCLUSION

In view of the above, each of the presently pending claims in the application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. The Examiner is invited to contact the undersigned with respect to any unresolved issues remaining in this application.

Respectfully submitted,



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to nondetectable levels in chromoplasts. Piechulla *et al.*, *Plant Mol. Biol.* (1986) 7:367-376.

Summary of the Invention

Novel methods and DNA constructs are provided for transforming plants employing T-DNA and a Ti- or Ri-plasmid for heterologous DNA introduction and integration into the plant genome. Transformation without gall formation of plant cells which have historically not been *Agrobacterium* hosts is achieved with successful expression of the heterologous DNA. Additionally, DNA constructs are provided which are employed in manipulating plant cells to provide for regulated transcription, such as light inducible transcription, in a plant tissue or plant part of interest at particular stages of plant growth or in response to external control. Particularly, transcriptional regions from seed storage proteins, seed coat proteins or acyl carrier protein are joined to other than the homologous gene and introduced into a plant cell host for integration into the genome to provide for seed-specific transcription. The constructs provide for modulation of expression of endogenous products as well as production of exogenous products in the seed. Novel DNA constructions also are provided employing a fruit-specific promoter, particularly a promoter from a gene active beginning at or shortly after anthesis or beginning at the breaker stage, joined to a DNA sequence of interest and a transcriptional termination region. A DNA construct may be introduced into a plant cell host for integration into the genome and transcription regulated at a time at or subsequent to anthesis. In this manner, high levels of RNA and, as appropriate, polypeptides, may be achieved during formation and/or ripening of fruit.

Also of interest is a transcriptional initiation region which is activated at or shortly after anthesis, so that in the early development of the fruit, it provides the desired level of transcription of the sequence of interest. Normally, the sequence of interest will be involved in affecting the process in the early formation of the fruit or providing a property which is desirable during the growing (expansion) period of the fruit, or at or after harvesting.

The ripening stages of the tomato may be broken down into mature green, breaker, turning, pink, light red and red. Desirably, the transcriptional initiation region maintains its activity during the expansion and maturation of the green fruit, more desirably continues active through the ripening or red fruit period. Comparable periods for other fruit are referred to as stages of ripening. The invention is not limited to those transcriptional initiation regions which are activated at or shortly after anthesis but also includes transcriptional initiation regions which are activated at any of the ripening stages of the fruit. An example of a fruit-specific transcriptional initiation region is the one referred to as 2A11 which regulates the expression of a 2A11 cDNA sequence described in the Experimental section. The 2A11 transcriptional initiation region provides for an abundant messenger, being activated at or shortly after anthesis and remaining active until the red fruit stage. The expressed protein is a sulfur-rich protein similar to other plant storage proteins in sulfur content and size.

Also of interest is a transcriptional initiation region which regulates expression of the enzyme polygalacturonase, an enzyme which plays an important role in fruit softening and/or rotting. The polygalacturonase

The following has been received in the U.S. Patent Office on the date stamped hereon:

- [X] Patent Application, 81 pps specification, 5 pps claims, 1 pps abstract
- [X] Drawings: 10 sheets of ~~informal~~ / formal
- [X] Application Transmittal
- [X] Return receipt postcard
- [X] ~~Response~~ Amendment preliminary
- [ ] Issue Fee Transmittal
- [ ] Notice of Appeal
- [ ] Appeal Brief(3 copies) ____ pages
- [X] PTO Box# PATENT APPLICATION
- [X] Express Mail Label EL737340911US
- [ ] Other _____
- [X] Executed/~~unexecuted~~ Declaration/POA copy
- [X] Assignment copy
- [ ] Verified Small Entity Statement
- [ ] Rule 132 Declaration
- [ ] 312 Amendment after Allowance
- [ ] Notice to File Missing Parts of App.
- [ ] Information Disclosure Statement
- [ ] Petition for Extension of Time
- [ ] Certificate of Correction
- [X] ~~Recommended~~, IDS Statement PTO-1449 [No. of References 10]
- [ ] Status Inquiry
- [X] Check No. 1307 in amount of $ 262 -

Serial No.: NYA Attorney Docket No.: CGNE.099.04US

Attorney/Secretary: ~~RPY/LLW~~ Mailing Date : 2-12-01

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